

FORM PTO-1449  
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0652.2010000/EKS/PSC

APPLICATION NO.  
09/446,317

APPLICANT  
Wagner et al.

GROUP  
1632

102(e) DATE  
April 17, 2000

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
						Yes X No
PS	AL1	FR 2 362 156	03/17/1978	France		Yes X No
PS	AM1	WO 93/07283	04/15/1993	WIPO		Yes No
PS	AN1	WO 95/28494	10/26/1995	WIPO		Yes No
PS	AO1	WO 96/21036	07/11/1996	WIPO		Yes No
	AP					

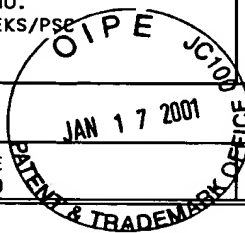
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

PS	AR	1	Kirchheis, R. et al., "Coupling of cell-binding ligands to polyethylenimine for targeted gene delivery," <i>Gene Therapy</i> 4:409-418, Stockton Press (1997)
PS	AS	1	Plank, C. et al., "Activation of the Complement System by Synthetic DNA Complexes: A Potential Barrier for Intravenous Gene Delivery," <i>Human Gene Therapy</i> 7:1437-1446, Mary Ann Liebert, Inc. (1996)
PS	AT	1	Derwent, File 351, English language abstract of FR 2 362 156.
EXAMINER			DATE CONSIDERED 2/26/01

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RS	AR	2	Abdallah, B. <i>et al.</i> , "A Powerful Nonviral Vector for <i>In Vivo</i> Gene Transfer into the Adult Mammalian Brain: Polyethylenimine," <i>Human Gene Ther.</i> 7:1947-1954, Mary Ann Liebert, Inc. (October 1996)
RS	AS	2	Absolom, D.R., "Opsonins and Dysopsonins: An Overview," <i>Methods in Enzymology</i> 132:281-318, Academic Press, Inc. (1986)
RS	AT	2	Abuchowski, A. <i>et al.</i> , "Cancer Therapy with Chemically Modified Enzymes. I. Antitumor Properties of Polyethylene Glycol-Asparaginase Conjugates," <i>Cancer Biochem. Biophys.</i> 7:175-186, Gordon and Breach Science Publishers, Inc. (1984)

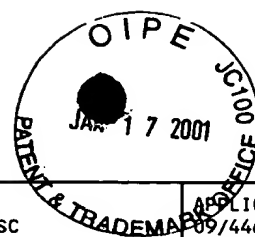
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PS	AR	3	Allen, T.M. <i>et al.</i> , "Liposomes containing synthetic lipid derivatives of poly(ethylene glycol) show prolonged circulation half-lives in vivo," <i>Biochim. et Biophys. Acta</i> 1066:29-36, Elsevier Science Publishers B.V. (1991)
PS	AS	3	Beauchamp, C.O. <i>et al.</i> , "A New Procedure for the Synthesis of Polyethylene Glycol-Protein Adducts; Effects on Function, Receptor Recognition, and Clearance of Superoxide Dismutase, Lactoferrin, and $\alpha_2$ -Macroglobulin," <i>Analytical Biochem.</i> 131:25-33, Academic Press, Inc. (1983)
PS	AT	3	Blume, G. and G. Cevc, "Liposomes for the sustained drug release in vivo," <i>Biochim. et Biophys. Acta</i> 1029:91-97, Elsevier Science Publishers B.V. (1990)

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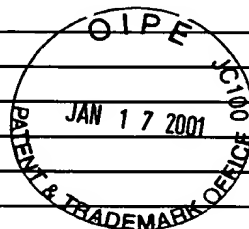
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RS	AR	4	Boussif, O. <i>et al.</i> , "A versatile vector for gene and oligonucleotide transfer into cells in culture and <i>in vivo</i> : Polyethylenimine," <i>Proc. Natl. Acad. Sci. USA</i> 92:7297-7301, National Academy of Sciences of the USA (1995)
RS	AS	4	Boussif, O. <i>et al.</i> , "Optimized galenics improve <i>in vitro</i> gene transfer with cationic molecules up to 1000-fold," <i>Gene Ther.</i> 3:1074-1080, Stockton Press (December 1996)
RS	AT	4	Chamow, S.M. <i>et al.</i> , "Modification of CD4 Immunoaderisin with Monomethoxypoly(ethylene glycol) Aldehyde via Reductive Alkylation," <i>Bioconj. Chem.</i> 5:133-140, American Chemical Society (1994)

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PS	AR	5	Chonn, A. <i>et al.</i> , "The Role of Surface Charge in the Activation of the Classical and Alternative Pathways of Complement by Liposomes," <i>J. Immunol.</i> 146:4234-4241, The American Association of Immunologists (1991)
PS	AS	5	Chonn, A. <i>et al.</i> , "Association of Blood Proteins with Large Unilamellar Liposomes <i>in Vivo</i> ," <i>J. Biol. Chem.</i> 267:18759-18765, The American Society for Biochemistry and Molecular Biology, Inc. (1992)
2S	AT	5	Delgado, C. <i>et al.</i> , "Coupling of Poly(ethylene glycol) to Albumin under Very Mild Conditions by Activation with Tresyl Chloride: Characterization of the Conjugate by Partitioning in Aqueous Two-Phase Systems," <i>Biotechnol. Appl. Biochem.</i> 12:119-128, Academic Press, Inc. (1990)

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RS	AR	6	Dust, J.M. <i>et al.</i> , "Proton NMR Characterization of Poly(ethylene glycols) and Derivatives," <i>Macromolecules</i> 23:3742-3746, American Chemical Society (1990)
RS	AS	6	Elling, L. and M.-R. Kula, "Immunoaffinity Partitioning: Synthesis and Use of Polyethylene Glycol-Oxirane for Coupling to Bovine Serum Albumin and Monoclonal Antibodies," <i>Biotechnol. &amp; Appl. Biochem.</i> 13:354-362, Academic Press, Inc. (1991)
RS	AT	6	Harris, J.M. <i>et al.</i> , "New Polyethylene Glycols for Biomedical Applications," <i>Polymer Preprints</i> 30:356-357, American Chemical Society (1989)

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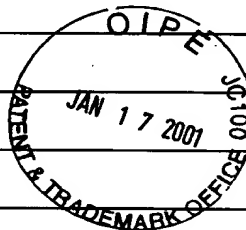
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RS	AR	Z	Hodgson, C.P., "The Vector Void in Gene Therapy," <i>Bio/Technology</i> 13:222-225, Nature Publishing Company (1995)
RS	AS	Z	Kirpotin, D. <i>et al.</i> , "Sterically Stabilized Anti-HER2 Immunoliposomes: Design and Targeting to Human Breast Cancer Cells <i>in Vitro</i> ," <i>Biochem.</i> 36:66-75 (January 1997)
RS	AT	Z	Klibanov, A.L. <i>et al.</i> , "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes," <i>FEBS Letters</i> 268:235-237, Elsevier Publishers B.V. (1990)

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RS	AR	8	Klibanov, A.L. <i>et al.</i> , "Activity of amphipathic poly(ethylene glycol) 5000 to prolong the circulation time of liposomes depends on the liposome size and is unfavorable for immunoliposome binding to target," <i>Biochim. et Biophys. Acta</i> 1062:142-148, Elsevier Science Publishers B.V. (1991)
RS	AS	8	Mayhew, E.G. <i>et al.</i> , "Pharmacokinetics and Antitumor Activity of Epirubicin Encapsulated in Long-Circulating Liposomes Incorporating a Polyethylene Glycol-Derivatized Phospholipid," <i>Int. J. Cancer</i> 51:302-309, Wiley-Liss, Inc. (1992)
RS	AT	8	Moghimi, S.M. <i>et al.</i> , "Coating particles with a block co-polymer (poloxamine-908) suppresses opsonization but permits the activity of dysopsonins in the serum," <i>Biochim. et Biophys. Acta</i> 1179:157-165, Elsevier Science Publishers B.V. (1993)

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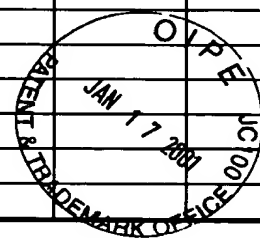
RS	AR	2	Mori, A. <i>et al.</i> , "Influence of the steric barrier activity of amphipathic poly(ethyleneglycol) and ganglioside GM <sub>1</sub> on the circulation time of liposomes and on the target binding of immunoliposomes in vivo," <i>FEBS Letters</i> 284:263-266, Elsevier Science Publishers B.V. (1991)
RS	AS	2	Nakamura, A. <i>et al.</i> , "Anchimeric Assistance in the Intramolecular Reaction of Glucose-dehydrogenase-Polyethylene Glycol NAD Conjugate," <i>J. Biol. Chem.</i> 261:16792-16794, The American Society of Biological Chemists, Inc. (1986)
RS	AT	2	Nilsson, K. and K. Mosbach, "Immobilization of Ligands with Organic Sulfonyl Chlorides," <i>Methods in Enzymology</i> 104:56-69, Academic Press, Inc. (1984)

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RS	AR	10	Papahadjopoulos, D. <i>et al.</i> , "Sterically stabilized liposomes: Improvements in pharmacokinetics and antitumor therapeutic efficacy," <i>Proc. Natl. Acad. Sci. USA</i> 88:11460-11464, National Academy of Sciences of the USA (1991)
RS	AS	10	Pitha, J. <i>et al.</i> , "Detergents Linked to Polysaccharides: Preparation and Effects on Membranes and Cells," <i>Eur. J. Biochem.</i> 94:11-18, Springer-Verlag (1979)
RS	AT	10	Sarin, V.K. <i>et al.</i> , "Quantitative Monitoring of Solid-Phase Peptide Synthesis by the Ninhydrin Reaction," <i>Analytical Biochem.</i> 117:147-157, Academic Press, Inc. (1981)

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RS	AR	11	Senior, J. <i>et al.</i> , "Influence of surface hydrophilicity of liposomes on their interaction with plasma protein and clearance from the circulation: studies with poly(ethylene glycol)-coated vesicles," <i>Biochim. et Biophys. Acta</i> 1062:77-82, Elsevier Science Publishers B.V. (1991)
RS	AS	11	Torchilin, V.P. <i>et al.</i> , "Targeted accumulation of polyethylene glycol-coated immunoliposomes in infarcted rabbit myocardium," <i>FASEB J.</i> 6:2716-2719, The Federation of American Societies for Experimental Biology (1992)
RS	AT	11	Torchilin, V.P. <i>et al.</i> , "Amphiphilic vinyl polymers effectively prolong liposome circulation time in vivo," <i>Biochim. et Biophys. Acta</i> 1195:181-184, Elsevier Science B.V. (1994)

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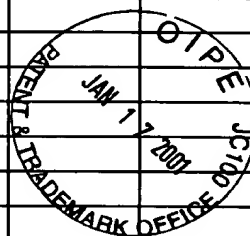
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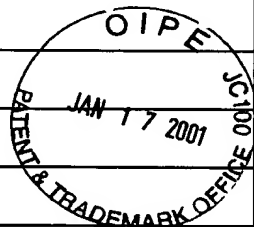
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RS	AR	12	Torchilin, V.P. and M.I. Papisov, "Why Do Polyethylene Glycol-Coated Liposomes Circulate So Long?," <i>J. Liposome Res.</i> 4:725-739, Marcel Dekker, Inc. (1994)
RS	AS	12	Wirth, P. <i>et al.</i> , "Chemical Modification of Horseradish Peroxidase with Ethanal-Methoxypolyethylene Glycol: Solubility in Organic Solvents, Activity, and Properties," <i>Bioorganic Chem.</i> 19:133-142, Academic Press, Inc. (1991)
RS	AT	12	Woodle, M.C. <i>et al.</i> , "Sterically Stabilized Liposomes: Physical and Biological Properties," <i>J. Drug Targeting</i> 2:397-403, Harwood Academic Publishers GmbH (1994)

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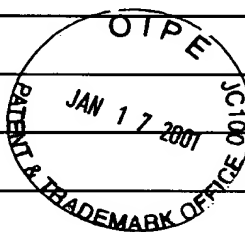
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No



## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

27	AR	13	Yoshinga, K. and J. M. Harris, "Effects of Coupling Chemistry on the Activity of Poly(ethylene glycol)-Modified Alkaline Phosphatase," <i>J. Bioactive &amp; Compatible Polymers</i> 4:17-24, Technomic Publishing Co., Inc. (1989)
25	AS	13	Yoshioka, H., "Surface modification of haemoglobin-containing liposomes with polyethylene glycol prevents liposome aggregation in blood plasma," <i>Biomaterials</i> 12:861-864, Butterworth-Heinemann Ltd. (1991)
25	AT	13	Zalipsky, S. and G. Barany, "Facile Synthesis of $\alpha$ -Hydroxy- $\omega$ -Carboxymethylpolyethylene Oxide," <i>J. Bioactive &amp; Compatible Polymers</i> 5:227-231, Technomic Publishing Co., Inc. (1990)

EXAMINER

DATE CONSIDERED

2/26/01

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
0652.2010000/EKS/PSCAPPLICATION NO.  
09/446,317  
(CPA filed on December 29,  
2000)APPLICANT  
WAGNER *et al.*§ 102 (e) DATE  
April 17, 2000GROUP  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

RS	AR	14	Zalipsky, S., "Synthesis of an End-Group Functionalized Polyethylene Glycol-Lipid Conjugate for Preparation of Polymer-Grafted Liposomes," <i>Bioconj. Chem.</i> 4:296-299, American Chemical Society (1993)
RS	AS	14	Zalipsky, S. <i>et al.</i> , "Poly(ethylene glycol)-Grafted Liposomes with Oligopeptide or Oligosaccharide Ligands Appended to the Termini of the Polymer Chains," <i>Bioconj. Chem.</i> 8:111-118, American Chemical Society (March/April 1997)
RS	AT	14	Boletta, A. <i>et al.</i> , "Nonviral Gene Delivery to the Rat Kidney with Polyethylenimine," <i>Human Gene Ther.</i> 8:1243-1251 (July 1997)

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DATE CONSIDERED

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